Application Serial No.: 10/034,033 Amendment dated June 27, 2006 Reply to Office Action of April 28, 2006

REMARKS

In response to the Office Action mailed April 28, 2006, Applicant respectfully requests the Examiner to reconsider the above-captioned application.

Amendment to Specification

The related applications paragraph of the specification has been updated to state that U.S. Application Ser. No. 10/634,655 is now U.S. Pat. No. 7,011,682.

Rejection of Claims 1-3 and 7-11 under 35 U.S.C. § 103(a)

The Examiner rejects claims 1-3 and 7-11 under 35 U.S.C. §103(a) as being unpatentable over Vidlund et al. (USPAP 2003/0130731) in view of Liddicoat et al. (USPN 6,790,231) and Alferness et al. (USPAP 2003/0105520).

The Examiner asserts that Vidlund et al. disclose a system for remodeling a mitral valve annulus with all the elements of claim 1, but is silent to a control on the catheter for reversibly transforming the implant between the first flexible configuration and the second remodeling configuration. The Examiner then asserts that Liddicoat et al. teach an apparatus for reducing mitral regurgitation wherein a wire is pushed and pulled to reversibly move an implant body to a configuration that forces the posterior annulus anteriorly from within the coronary sinus. The Examiner then asserts that it would have been obvious to look to the teachings of Liddicoat et al. to modify the system of Vidlund et al. by making the implant reversibly movable between the first and second configurations by pulling a pushing the wire actuation mechanism. Examiner then asserts that Alferness et al. teach a system for effecting the mitral valve annulus geometry wherein an implant is detachably carried by a delivery catheter having a lumen by being slideably received in the lumen. Finally, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to look to the teachings of Alferness et al. to modify the system of Vidlund et al. such that the implant is deployed in the coronary sinus using a similar technique. The Examiner reasons that, by including a coupling to the actuation mechanism and a lock to the proximal end of the implant, a control on the catheter in the form of a tension cable with coupling can be used to reversibly JUN. 27. 2006 3:48PM EDWARDS LEGAL Application Serial No.: 10/634,653 Amendment dated June 27, 2006 Reply to Office Action of April 28, 2006

transform the implant between the first flexible configuration and the second remodeling configuration by pushing or pulling and then removing the delivery catheter and control after achieving the desired configuration.

Applicant disagrees with the Examiner's characterization of the cited references. Vidlund et al. fail to teach or suggest an implant having a first, flexible configuration and a second, rigid configuration. The implant (110h) illustrated in Figure 4h of Vidlund et al. is not in a flexible configuration. Rather, the shape of the implant is directly controlled by the position of the actuation mechanism (90) relative to the implant. The curvature of the implant can only be altered by pulling the actuation mechanism and therefore the implant is not in a "flexible configuration" as claimed by Applicant.

On the other hand, Applicant claims an implant that is reversibly movable between a first, <u>flexible</u> configuration for delivery to a site adjacent the annulus of the mitral valve and a second, <u>rigid</u> configuration for remodeling the mitral valve annulus. One preferred embodiment of Applicant's claimed invention is illustrated in Figures 8A and 8B. As can be seen in Figure 8A, in the absence of tension on a filament, the implant has a flexible configuration for delivery to a treatment site. However, when tension is applied to the filament as shown in Figure 8B, the implant transforms from the flexible configuration to a rigid configuration for remodeling the mitral valve annulus. (See paragraph [0127] of the present application.)

In the present Office Action, the Examiner has combined Liddicoat et al. with the previously cited references (Vidlund et al. and Alferness et al.) to reject the claimed invention. More particularly, the Examiner asserts that Liddicoat et al. teaches an apparatus for reducing mitral regurgitation wherein a wire is pushed and pulled to reversibly move an implant body to a configuration that forces the posterior annulus anteriorly from within the coronary sinus. However, Applicant notes that Liddicoat et al. do not teach or suggest an implant that is reversible between a first, flexible configuration and a second, rigid configuration. The wire disclosed by Liddicoat et al. merely provides a means for adjusting the curvature of the body. Liddicoat et al. do not disclose or suggest an implant wherein the rigidity of the body can be changed from flexible to rigid and back to flexible.

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NO. 3605 P. 7/8

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Although Applicant believes that the previously submitted claims are distinguishable over the cited references, Applicant has amended independent claim 1 to further clarify preferred features of the present invention and thereby expedite allowance of the present application. Claim 1 now further recites an "implant including a guidewire lumen adapted to slideably engage a guidewire." Applicant has also canceled claims 4, 5 and 7-11 and has added new claims 12-14.

None of the cited references teaches or suggests an implant having a guidewire lumen. Furthermore, as discussed above, none of the cited references teaches or suggests an implant that is reversibly movable between a first, flexible configuration for delivery to a site adjacent the annulus of the mitral valve and a second, rigid configuration for remodeling the mitral valve annulus. Therefore, in view of the above amendments and remarks, Applicant respectfully requests that the Examiner withdraw the rejections of the claims under 35 U.S.C. §103(a).

Rejection of Claims 4 and 5 under 35 U.S.C. § 103(a)

The Examiner rejects claims 4 and 5 under 35 U.S.C. §103(a) as being unpatentable over Vidlund et al., Liddicoat et al. and Alferness et al., and further in view of Adams et al. (USPAP 2003/0083538). Dependent claims 4 and 5 have been cancelled, thereby rendering the rejection moot.

Rejection of Claim 6 under 35 U.S.C. § 103(a)

The Examiner rejects claim 6 under 35 U.S.C. §103(a) as being unpatentable over Vidlund et al., Liddicoat et al. and Alferness et al., and further in view of Solem et al. (USPN 6,210,432). For the reasons discussed above, Applicant believes that claim 1 is allowable. Accordingly, dependent claim 6, which further recites a coating on the implant, should also be allowed.

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Fees Due to File This Amendment

Prior to the pending Office Action, a fee was paid for the original 11 claims, with 3 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the original number of claims, and thus no claim fees are believed to be due to file this amendment.

CONCLUSION

Should the Examiner have any questions, the Examiner is encouraged to contact the attorney of record at the telephone number indicated below.

Respectfully submitted,

Date: June 27, 2006

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